



Connecticut Department of

**ENERGY &
ENVIRONMENTAL
PROTECTION**

**BUREAU OF AIR MANAGEMENT
NEW SOURCE REVIEW PERMIT
TO CONSTRUCT AND OPERATE A STATIONARY SOURCE**

Issued pursuant to Title 22a of the Connecticut General Statutes (CGS) and Section 22a-174-3a of the Regulations of Connecticut State Agencies (RCSA).

Owner/Operator	Covidien LP
Address	195 McDermott Road, North Haven, CT 06473
Equipment Location	195 McDermott Road, North Haven, CT 06473
Equipment Description	Ethylene Oxide Sterilizer #ST-B (formerly #ST-8)
Collateral Conditions	This permit contains combined Maximum Annual Sterilant Consumption and Maximum Allowable Emissions limits for both Ethylene Oxide Sterilizers #ST-B and #ST-A (NSR Permit No. 135-0143).
Town-Permit Numbers	135-0144
Premises Number	68
Stack Number	17
Modification Issue Date	MAR 07 2016
Prior Permit Issue Date(s)	November 19, 2012 November 8, 2011
Expiration Date	None

for Anne M. Klee
Robert J. Klee
Commissioner

March 7, 2016
Date

I CERTIFY THAT THIS IS A TRUE COPY OF THE ORIGINAL
James J. Sheedy 3-7-16

79 Elm Street, Hartford, CT 06106-5127
www.ct.gov/deep
Affirmative Action/Equal Opportunity Employer

ORIGINAL

Covidien_North Haven_2016_Permit_#135-0144_NonCBI - 000001

This permit specifies necessary terms and conditions for the operation of this equipment to comply with state and federal air quality standards. The Permittee shall at all times comply with the terms and conditions stated herein.

PART I. DESIGN SPECIFICATIONS

A. General Description

Covidien LP operates two sterilization systems (each consisting of a sterilization chamber and a primary aeration room, as well as two secondary aeration rooms that are shared by both systems), referred to throughout this permit as Sterilizers #ST-A and #ST-B. The units are used to sterilize medical devices. The devices are introduced to the sterilization chamber and sterilized using a mixture of ethylene oxide, nitrogen and steam. The sterilized product is then off-gassed; first in a primary aeration room and then a secondary aeration room. All sterilizer and primary aeration room exhausts and vents are ducted to a single stack equipped with a balancer and oxidizer (Stack E-401). There is a combined exhaust stack for the two secondary aeration room exhausts, which exhausts direct to atmosphere due to the low levels of ethylene oxide present (Stack E-500). This permit covers sterilizer #ST-B. Sterilizer #ST-A is covered by permit no. 135-0143. There are conditions throughout this permit that apply to both sterilization systems combined. Any such condition is so specified.

B. Equipment Design Specifications

Equipment: Ethylene Oxide Sterilization Chamber and associated Primary and Secondary Aeration Rooms

C. Control Equipment Design Specifications

1. Equipment: Catalytic Oxidizer
Make: LESNI A/S
Model Name: CAP 12000
Catalyst Type: Low Temperature Metal Oxide Catalyst
2. Equipment: Balancer
Make: LESNI A/S
Model Name: CAP LKV 800

D. Emissions Control

1. Stack No.: E-401
Ethylene Oxide: 99.9% minimum control efficiency or a maximum concentration of 1.0 ppm in outlet gas; whichever is less stringent.
2. Stack No.: E-500
Ethylene Oxide: Maximum concentration of 1.0 ppm in outlet gas.

E. Stack Parameters

1. Stack No.: E-401
 - a. Minimum Gas Flowrate (acfm): 4,000
 - b. Minimum Distance to Property Line (ft): 247

- c. Minimum Stack Height (ft): 58
 - d. Equipment Connected to this Stack: Sterilizer chambers' #ST-B and #ST-A and each sterilizer's primary aeration room
2. Stack No.: E-500
- a. Minimum Gas Flowrate (acfm): 5,000
 - b. Minimum Distance to Property Line (ft): 248
 - c. Minimum Stack Height (ft): 58
 - d. Equipment Connected to this Stack: Polymer and Suture Secondary Aeration Rooms

PART II. OPERATIONAL CONDITIONS

A. Equipment

- 1. Allowable Sterilant: Ethylene Oxide
- 2. Maximum Allowable Sterilant Consumption: 50 lb/batch
- 3. Maximum Number of Batches: 3 batches/day; 1,095 batches/yr
- 4. Maximum Annual Sterilant Consumption for Sterilizers' #ST-B and #ST-A combined: 54.75 tons/consecutive twelve (12) month period

B. Control Equipment

- 1. Catalytic Oxidizer
 - a. Type of Fuel: Natural Gas
 - b. Maximum Annual Usage: 11.63 MMcf
 - c. Maximum Heat Input: 1.365 MMBtu/hr
 - d. Catalyst Type: Low Temperature Metal Oxide Catalyst

PART III. ALLOWABLE EMISSION LIMITS

The Permittee shall not cause or allow this equipment to exceed the emission limits stated herein at any time.

The following emission limits are for Sterilizers' #ST-B and #ST-A combined.

A. Criteria Pollutants

- 1. Sterilizers

Equipment	Pollutant	lb/hr	ppmv (24-hr avg.)	TPY
Sterilizers and Primary Aeration Rooms	VOC (Ethylene Oxide)	0.059	1.0	0.257
Secondary Aeration Rooms	VOC (Ethylene Oxide)	0.086	1.0	0.375

2. Catalytic Oxidizer (Natural Gas Combustion)

Pollutant	lb/hr
PM10/PM2.5	0.010
SOx	0.001
NOx	0.133
VOC	0.007
CO	0.112
Pb	0.000

3. Total Emissions

Pollutant	TPY
PM10/PM2.5	0.044
SOx	0.003
NOx	0.582
VOC (includes Ethylene Oxide)	0.663
CO	0.488
Pb	0.000

B. Hazardous Air Pollutants

This equipment shall not cause an exceedance of the Maximum Allowable Stack Concentration (MASC) for any hazardous air pollutant (HAP) emitted and listed in RCSA Section 22a-174-29. The Permittee shall be allowed to use the adjustment factor in RCSA Section 22a-174-29(i). [STATE ONLY REQUIREMENT]

C. Demonstration of compliance with the above emission limits may be met by calculating the emissions using emission factors from the following sources:

- Natural Gas Combustion: emission factors from AP-42, 5th edition Table 1.4-1 and 1.4-2;
- Ethylene Oxide: concentration monitoring in accordance with 40 CFR §63.364, material balance and performance test results.

The commissioner may require other means (e.g. stack testing) to demonstrate compliance with the above emission limits, as allowed by state or federal statute, law or regulation.

PART IV. MONITORING, RECORD KEEPING AND REPORTING REQUIREMENTS

A. Monitoring Requirements

1. For Stack E-401, the Permittee shall measure and record once per hour the ethylene oxide concentration at the outlet to the atmosphere or continuously monitor and record the oxidation temperature at the outlet to the catalyst bed.
2. For Stack E-500, the Permittee shall measure and record once per hour the ethylene oxide concentration at the outlet to the atmosphere.

B. Record Keeping Requirements

1. The Permittee shall make and maintain records of the amount of ethylene oxide used monthly and during each twelve consecutive months. The consecutive twelve month usage shall be calculated by adding the current month's usage to that of the previous eleven months.
2. The Permittee shall maintain records of the dates when the oxidizer catalyst is changed.
3. For the stacks which the Permittee is measuring and recording the ethylene oxide concentration once per hour, the Permittee shall compute and record a 24-hour average daily.
4. Records demonstrating compliance with this permit shall be kept on site, for a period no less than the past five calendar years, and be made available upon request to the Bureau of Air Management.

C. Work Practice Standards

1. For Stack E-401, the Permittee shall comply with one of the work practices outlined in 40 CFR 63.363(b)(4).

PART V. STACK EMISSION TEST REQUIREMENTS

Stack emission testing shall be performed in accordance with the Emission Test Guidelines available on the DEEP website.

- A.** For Stack E-401, the Permittee shall conduct recurrent emission testing for ethylene oxide within five years from the date of the previous stack test to demonstrate compliance with the lb/hr and ppm limits, as well as the overall control efficiency. Emission testing, as specified in 40 CFR 63.363(b)(4)(i), used to comply with the work practices requirement, may be used to fulfill the recurrent emission testing requirement.

PART VI. OPERATION AND MAINTENANCE REQUIREMENTS

- A.** The Permittee shall operate and maintain this equipment in accordance with the manufacturer's specifications and written recommendations.
- B.** The Permittee shall properly operate the control equipment at all times that this equipment is in operation and emitting air pollutants.

PART VII. SPECIAL REQUIREMENTS

- A.** The Permittee shall not cause or permit the emission of any substance or combination of substances which creates or contributes to an odor beyond the property boundary of the premises that constitutes a nuisance as set forth in RCSA Section 22a-174-23. [STATE ONLY REQUIREMENT]
- B.** The Permittee shall operate this facility at all times in a manner so as not to violate or contribute significantly to the violation of any applicable state noise control regulations, as

set forth in RCSA Sections 22a-69-1 through 22a-69-7.4. [STATE ONLY REQUIREMENT]

PART VIII. ADDITIONAL TERMS AND CONDITIONS

- A.** This permit does not relieve the Permittee of the responsibility to conduct, maintain and operate the regulated activity in compliance with all applicable requirements of any federal, municipal or other state agency. Nothing in this permit shall relieve the Permittee of other obligations under applicable federal, state and local law.
- B.** Any representative of the DEEP may enter the Permittee's site in accordance with constitutional limitations at all reasonable times without prior notice, for the purposes of inspecting, monitoring and enforcing the terms and conditions of this permit and applicable state law.
- C.** This permit may be revoked, suspended, modified or transferred in accordance with applicable law.
- D.** This permit is subject to and in no way derogates from any present or future property rights or other rights or powers of the State of Connecticut and conveys no property rights in real estate or material, nor any exclusive privileges, and is further subject to any and all public and private rights and to any federal, state or local laws or regulations pertinent to the facility or regulated activity affected thereby. This permit shall neither create nor affect any rights of persons of municipalities who are not parties to this permit.
- E.** Any document, including any notice, which is required to be submitted to the commissioner under this permit shall be signed by a duly authorized representative of the Permittee and by the person who is responsible for actually preparing such document, each of whom shall certify in writing as follows: "I have personally examined and am familiar with the information submitted in this document and all attachments thereto, and I certify that based on reasonable investigation, including my inquiry of those individuals responsible for obtaining the information, the submitted information is true, accurate and complete to the best of my knowledge and belief. I understand that any false statement made in the submitted information may be punishable as a criminal offense under Section 22a-175 of the Connecticut General Statutes, under Section 53a-157b of the Connecticut General Statutes, and in accordance with any applicable statute."
- F.** Nothing in this permit shall affect the commissioner's authority to institute any proceeding or take any other action to prevent or abate violations of law, prevent or abate pollution, recover costs and natural resource damages, and to impose penalties for violations of law, including but not limited to violations of this or any other permit issued to the Permittee by the commissioner.
- G.** Within 15 days of the date the Permittee becomes aware of a change in any information submitted to the commissioner under this permit, or that any such information was inaccurate or misleading or that any relevant information was omitted, the Permittee shall submit the correct or omitted information to the commissioner.
- H.** The date of submission to the commissioner of any document required by this permit shall be the date such document is received by the commissioner. The date of any notice by the commissioner under this permit, including but not limited to notice of approval or disapproval of any document or other action, shall be the date such notice is personally

delivered or the date three days after it is mailed by the commissioner, whichever is earlier. Except as otherwise specified in this permit, the word "day" means calendar day. Any document or action which is required by this permit to be submitted or performed by a date which falls on a Saturday, Sunday or legal holiday shall be submitted or performed by the next business day thereafter.

- I. Any document required to be submitted to the commissioner under this permit shall, unless otherwise specified in writing by the commissioner, be directed to: Office of Director; Engineering & Enforcement Division; Bureau of Air Management; Department of Energy and Environmental Protection; 79 Elm Street, 5th Floor; Hartford, Connecticut 06106-5127.

Covidien LP
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